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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/597,179 06/20/00 ROONEY

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EXAMINER

QM12/0801

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CLASSIFIED P
ART UNIT PAPER NUMBER

3736
DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/597,179

Applicant(s)

Rooney et al.

Examiner

Pamela Wingood

Art Unit

3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 15, 2001.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 22-26 and 28-56 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 22-26, 28-35, 37-51, and 53-56 is/are rejected.

7) ☒ Claim(s) 36 and 52 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

Art Unit: 3736

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 41-45, 50, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline.

Kline discloses a guidewire having an inner composite core and a unitary round coil with an outer lubricious coating composed of a second material that extends distal of the distal portion of the core.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 22-26, 28, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kline in view of Deem.

Art Unit: 3736

Kline disclose a guidewire having an inner composite core and a unitary round coil with an outer lubricious coating composed of a second material that extends distal of the distal portion of the core; however, it does not disclose a nickel titanium coil.

Deem discloses a core of a nickel titanium alloy in an analogous art for the purpose of achieving the desired properties of a core such as strength and torquability. (Col. 3, Ins.30-39). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device of Kline as shown by Deem because the use of a nickel titanium alloy is known to impart desired characteristics to the guidewire.

5. Claims 22-26, 30, 33-35, 38, 41-46, 49-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al in view of Deem.

Morrison et al discloses a guidewire having a tapered core of carbon steels as well as titanium (Col. 2, Ins. 5-10), and a varied pitched coil (Figs. 2 and 3) including a distal end(13) (Col. 2, Ins. 64-68) composed of stainless steel (Col. 2, Ins. 6), having a circular-cross section and extending the entire length of the guidewire (Fig. 1, Col. 2, Ins. 64-68), and at (19) a brazing compound to secure the coils to the core and at (18) a gold alloy slug that is necessarily radiopaque; however it does not disclose a core of a nickel titanium alloy.

Deem discloses a core of a nickel titanium alloy in an analogous art for the purpose of achieving the desired properties of a core such as strength and torquability. (Col. 3, Ins.30-39). It would have been obvious to a person of ordinary skill in the art at the time the invention was

Art Unit: 3736

made to have modified the device of Morrison et al. as shown by Deem because the use of a nickel titanium alloy is known to impart desired characteristics to the guidewire.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. and Deem as applied to claims 22-26, 30 and 33 above and further in view of Beisel.

Morrison et al. and Deem discloses the limitations above but does not disclose a precipitation hardened alloy as the second material.

Beisel discloses a device having a coil of a precipitation hardened alloy (Col. 12, lns. 27-32) in an analogous art for the purpose of imparting desirable properties. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison et al. as shown by Beisel because the treatment of the coils would impart desired coil stiffness and torquability to the device.

7. Claims 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. and Deem as applied to claims 22-26, 30, 33-35, 38, 41-46, 49-51 and 54 and further in view of Dubois.

Morrison et al. and Deem apply the limitations above but do not disclose a coil having a rectangular cross-section.

Dubois discloses a guidewire having a rectangular cross-section in an analogous art for the purpose of maintaining greater control over the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison

Art Unit: 3736

et al. and Deem as shown by Dubois because the rectangular configuration would more effectively transmit torque to the distal end of the device.

8. Claims 39, 40, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. and Deem as applied to claims 22-26, 30, 33-35, 38, 41-46, 49-51 and 54 above, and further in view of Fleischhacker et al. (705).

Morrison et al. and Deem disclose the limitations above but does not disclose the use of a multifilar cross-wound coil.

Fleischhacker et al. (705) discloses a multifilar cross-wound coil in an analogous art for the purpose of preventing kinking and transferring torque. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison et al. as shown by Fleischhacker (705) because the structure would ensure better control at the guidewire's distal tip.

9. Claims 31, 32, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. and Deem as applied to claims 22-26, 30, 33-35, 38, 41-46, 49-51 and 54 above, and further in view of McMahon.

Morrison et al. and Deem disclose the limitations above but do not disclose a distal polymeric tip that is radiopaque.

McMahon disclose a polymeric tip in an analogous art for the purpose of preventing patient trauma. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device of Morrison et al. and Deem as shown by

Art Unit: 3736

McMahon because the making the already radiopaque tip of softer material would provide a radiopaque tip that is also atraumatic.

Allowable Subject Matter

10. Claims 36 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Salmon et al. (5,458,585) discloses a catheter device with a precipitation hardened coil.

9. Kline et al. (3,749,086) discloses a guidewire having an outer coil that extends its full length and an inner composite core.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3736

CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

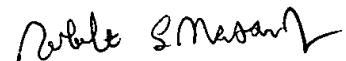
Response to Arguments

13. Applicant's arguments filed 5.15.01 have been fully considered but they are not persuasive. If Applicant reviews the newly applied reference and the prior rejection, the references do separately and in combination properly reject the above claims. Applicant is encouraged to submit argument supporting his position in the next action for review by the office.

Any questions regarding this application can be addressed to Pamela Wingood who can be reached on (703)308-2676.

Pamela Wingood
Patent Examiner

July 29, 2001



ROBERT L. NASSER
PRIMARY EXAMINER